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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,187	03/05/2001	Christina M. Grozinger	HUV-037.01	3390

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	18

DATE MAILED: 04/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,187	GROZINGER ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-77 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-77 are pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 9, 10, 15, 18-24, 27, 28 (in part), drawn to a DNA encoding SEQ ID NO:2, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

II. Claims 2, 11, 12, 15, 18-24, 27, 28 (in part), drawn to a DNA encoding SEQ ID NO:4, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

III. Claims 3, 12, 13, 15, 18-24, 27, 28 (in part), drawn to a DNA encoding SEQ ID NO:6, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

IV. Claims 4, 5 (in part) and 6, drawn to a DNA encoding SEQ ID NO:8, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

V. Claims 4, 5 (in part) and 7, drawn to a DNA encoding SEQ ID NO:8, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

VI. Claims 4, 5 (in part) and 8, drawn to a DNA encoding SEQ ID NO:8, a vector containing it, a cell transformed with the same and a method of making a polypeptide, classified in class 435, subclass 196.

VII. Claims 25 and 26, drawn to a non-human transgenic animal, classified in class 800, subclass 2.

VIII. Claims 29-33, drawn to an oligonucleotide and a kit comprising thereof, classified in class 536, subclass 24.31.

IX. Claims 34-36 (in part), drawn to an antibody against an *HDx* polypeptide, classified in class 530, subclass 387.1.

X. Claims 37-42 and 55-58 (in part), drawn to a polypeptide of SEQ ID NO:2, classified in class 435, subclass 196.

XI. Claims 43-48 and 55-58, 63-66 (in part), drawn to a polypeptide of SEQ ID NO:4, classified in class 435, subclass 196.

XII. Claims 49-54 and 55-58, 63-66 (in part), drawn to a polypeptide of SEQ ID NO:6, classified in class 435, subclass 196.

XIII. Claim 59, drawn to a polypeptide of SEQ ID NO:7, classified in class 435, subclass 196.

XIV. Claim 60, drawn to a polypeptide of SEQ ID NO:8, classified in class 435, subclass 196.

XV. Claim 61, drawn to a polypeptide of SEQ ID NO:9, classified in class 435, subclass 196.

XVI. Claim 62, drawn to a polypeptide of SEQ ID NO:10, classified in class 435, subclass 196.

XVII. Claims 67 and 68, drawn to methods of use of an agent, classified in class 435, subclass 375.

XVIII. Claims 69-71, drawn to methods of screening for agents that modulate *HDx* activity, classified in class 435, subclass 19.

XIX. Claims 72-77, drawn to a composition, a pharmaceutical composition and a library comprising a compound, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIX are patentably distinct because a DNA, polypeptide, an antibody, agent and a compound are different compounds each with its own chemical structure and function, and they have different utilities. A DNA molecule of inventions I-VI can be used for the production of a polypeptide of inventions X-XVI and as a hybridization probe. A polypeptide of inventions X-XVI can be obtained by a materially

different method such as by the biochemical purification or chemical synthesis and it can be used for the production of an antibody of invention IX and in a screening assay of invention XVIII. A DNA of inventions I-VI and an oligonucleotide of invention VIII are patentably distinct as having a different structure and utilities. An agent used in inventions XVII and a compound of invention XIX can be used for modulation activities of other biomolecules and for the production of antibodies.

While a polypeptide of inventions X-XVI is related to an antibody of invention IX as being cognate antigen, the structure of an antibody is unpredictable from the structure of the polypeptide of inventions X-XVI. An antibody of invention IX can cross-react with other polypeptides.

Inventions I-VI, VIII-XVI, XIX and invention VII are patentably distinct because a polypeptide, a DNA, an antibody, and a compound are single chemical compounds while a transgenic organism is a live organism comprising a vast number of compounds acting in accord.

Inventions X-XII and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a polypeptide of inventions X-XII can be used for the production of antibodies.

Inventions XVII and XVIII are patentably distinct because they are directed to materially different methods employing different compounds such as an agent and a polypeptide.

Each of inventions (I-VI) or each of inventions (X-XVI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

April 21, 2003